

DEPARTMENT OF THE ARMY  
CHEMICAL BIOLOGICAL MEDICAL SYSTEMS JOINT PROJECT  
MANAGEMENT OFFICE

BROAD AGENCY ANNOUNCEMENT  
MEDICAL CHEMICAL BIOLOGICAL RADIOLOGICAL AND  
NUCLEAR COUNTERMEASURE RESEARCH AND  
DEVELOPMENT

GENERAL INFORMATION &  
PROPOSAL PREPARATION

BAA 07-01

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FREDERICK, MARYLAND

# CHEMICAL BIOLOGICAL MEDICAL SYSTEMS JOINT PROJECT MANAGEMENT OFFICE

BAA 07-01

## I. PREFACE

The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) is organized into eight Joint Project Management Offices, each responsible for specific commodity areas. The Chemical Biological Medical Systems Joint Project Management Office (CBMS JPMO) consists of the Joint Vaccine Acquisition Program (JVAP), Medical Identification and Treatment Systems (MITS), and Transformational Medical Technologies Initiative (TMTI) Joint Product Management Offices (JPMOs). The medical CBRN countermeasures developed by the CBMS JPMO directly support the current, near-term, and far-term challenges by providing the capability to prevent, diagnose and treat the effects of chemical, radiological and biological warfare agents. The JVAP JPMO provides biological protection by ensuring Warfighters' immune systems are primed to protect them from selected threats. The MITS JPMO is responsible for the advanced development of U.S. Food and Drug Administration (FDA)-approved/licensed/cleared products for prophylaxis, treatment and diagnosis of CBRN agent exposure. The TMTI JPMO is developing and evaluating novel processes to accelerate the development and approval of medical CBRN countermeasures by leveraging lifecycle bioinformatics, enabling technologies, and other emerging technologies. General information on JPEO-CBD and subordinate JPMOs can be obtained from the JPEO-CBD website at <http://www.jpeocbd.osd.mil/>.

This Broad Agency Announcement (BAA) is intended to solicit pre-proposals for: 1) those parts of development not related to the development of a specific system or hardware procurement in accordance with (i) the Federal Acquisition Regulation (FAR) 35.016(a) and (ii) DoD Grant Regulations (DoDGARs) subject to section 2374 of Title 10 United State Code and 2) the development of prototypes in accordance with Section 845 of Public Law (P.L.) 103-160. The purpose of this BAA is to identify the best available science, and as such, there are no set-asides associated with any awards resulting from this BAA. Specific areas of interest are described in the "Areas of Interest" attachment. As to any resultant procurement contracts, this BAA is issued under the provisions of the Competition in Contracting Act of 1984 (P.L. 98-369), as implemented in the FAR at accordance. This Announcement provides a general description of CBMS JPMO's project areas, including specific areas of interest, general information, evaluation and selection criteria, and proposal preparation instructions. All Attachments that are required with the submission of a full proposal are described in the Mandatory Proposal Forms section of this announcement. **Proposals are sought from all eligible sources, including educational institutions, nonprofit organizations, and private industry. Generally, this announcement is continuously open; preliminary proposals (preproposals) may be submitted and will be evaluated at any time throughout the year. The availability of funds may limit the ability of the U.S. Government to make awards in specific areas, nevertheless preproposals are sought under this BAA announcement for all areas of interest described in the "Areas of Interest".**

**This announcement of the U.S. Government's current interests will be posted on the Grants.gov web portal (<http://www.grants.gov/>), the Federal Business Opportunity website (<http://www.fedbizopps.gov>), and the JPEO-CBD website.** From time to time, this BAA may be amended with announcements or calls for proposals. Additionally, the application process may be amended as other electronic application processes are implemented. All amendments to this BAA will be announced on the JPEO-CBD website, the Grants.gov web portal, and the Federal Business Opportunity website.

**To facilitate communication on both scientific and administrative matters relating to this BAA, a single email address may be used for all communication with CBMS JPMO. Please send all technical and administrative questions and inquiries to [cbmsbaa@amedd.army.mil](mailto:cbmsbaa@amedd.army.mil).**

Potential applicants are encouraged to discuss their proposal ideas with the CBMS technical staff. In addition to the address above, potential applicants may discuss their ideas with the Technical Contacts listed at the end of each area of interest.

Administrative questions concerning the preparation of preproposals or proposals should be addressed to U.S. Army Space and Missile Defense Command (USASMDC)/CBMS JPMO Grants Officer. They should be emailed to [cbmsbaa@amedd.army.mil](mailto:cbmsbaa@amedd.army.mil), faxed to 301-619-5069, ATTN: BAA 07-01, or mailed to the following address:

Chemical Biological Medical Systems  
ATTN: BAA 07-01  
64 Thomas Johnson Dr.  
Frederick, MD 21702

Issues with submitting applications through the Grants.gov web portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email [support@grants.gov](mailto:support@grants.gov). The Contact Center hours of operation are Monday-Friday, 7 AM to 9 PM Eastern Standard Time.

The Catalog of Federal Domestic Assistance (CFDA) can be accessed online at <http://www.cfda.gov>. The online CFDA provides access to a database of all Federal programs available to the grant community, including state, local and tribal Governments, academia and research institutions, commercial firms and not-for-profits. Included on the web site are contact information for the office that administers each program, instructions on how to apply for assistance, and several proposal writing guides. The CFDA number for this announcement is 12.360.

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### **III. ACRONYMS**

ACO	Administrative Contracting Officer
ACURO	Animal Care and Use Review Office
AOR	Authorized Organizational Representative
BAA	Broad Agency Announcement
CBDP	Chemical Biological Defense Program
CBMS JPMO	Chemical Biological Medical Systems Joint Project Management Office
CBRN	Chemical, Biological, Radiological, and Nuclear
CCR	Central Contractor Registry
CDRL	Contract Data Requirements List
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
CLINs	Contract Line Item Numbers
cGMP	current Good Manufacturing Processes
CWBS	Contract Work Breakdown Structure
DCAA	Defense Contract Audit Agency
DCMA	Defense Contract Management Agency
DFARS	DoD FAR Supplement
DoD	Department of Defense
DoDGARs	DoD Grant and Agreement Regulations
D-U-N-S®	Data Universal Number System
EPLS	Excluded Parties List System
EFT	Electronic Funds Transfer
FAR	Federal Acquisition Regulation

FDA	U.S. Food and Drug Administration
FCCM	Facilities Capital Cost of Money
FOIA	Freedom of Information Act
FY	U.S. Government Fiscal Year, which begins October 1
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
HRPO	Human Research Protection Office
IMS	Integrated Master Schedule
IAE	Integrated Acquisition Environment
JPEO-CBD	Joint Program Executive Office for Chemical and Biological Defense
JVAP JPMO	Joint Vaccine Acquisition Program Joint Product Management Office
MITJ JPMO	Medical Identification and Treatment Systems Joint Product Management Office
OMB	Office of Management and Budget
ORCA	Online Representations and Certifications Application
OSD	Office of the Secretary of Defense
OT	Other Transaction
P.L.	Public Law
POC	Point of Contact
RDT&E	Research, Development, Test, and Evaluation
SOW	Statement of Work
RFP	Request for Proposal
R&R	Research and Related
SF	Standard Form
SSA	Source Selection Authority
SSP	Source Selection Plan

TMTI JPMO	Transformational Medical Technologies Initiative Joint Product Management Office
TRL	Technology Readiness Level
USASMDC	U.S. Army Space and Missile Defense Command
USC	U.S. Code
WAWF	Wide-Area Work Flow
WBS	Work Breakdown Structure



## **IV. GENERAL INFORMATION**

### **A. CBMS JPMO AWARDS**

#### **1. Type of CBMS JPMO Awards.**

The CBMS JPMO contemplates the award of procurement contracts, grants, and other transactions for prototypes (Prototype OT) under this BAA in support of its mission to foster and/or conduct the advanced development of FDA-approved medical CBRN countermeasures. In the event of a conflict between this BAA and the Office of the Secretary of Defense (OSD) guide for Prototype OTs, the latter is the paramount consideration that CBMS JPMO will employ in the review and award of Prototype OT proposals. The purpose of this BAA is to identify the best available science, and as such, there are no set-asides associated with any awards resulting from this BAA due to the impracticality of reserving discrete or severable areas/elements of development in the cited areas of interest or to inapplicability.

Procurement contracts. Procurement contracts will be utilized to fund development activities that, while directly supporting a U.S. Government requirement, are not related to the development or procurement of a specific system. These efforts should be intended for developmental scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding, rather than focusing on a specific system, product, or medical countermeasure. Examples of the use of a procurement contract include a Good Laboratory Practices (GLP)-compliant animal toxicology study, or a Phase 1 clinical safety study.

OT for Prototype Projects. Section 845 of P.L. 103-160 authorizes the DoD to enter in to transactions other than contracts or grants for the purpose of developing weapons systems prototypes (Prototype OT). Prototypes are the quantities of a system (e.g., a drug or biologic) required to prove technical or manufacturing feasibility or evaluate military utility (e.g., approval by the FDA). The development of prototype FDA-approved medical CBRN countermeasures is an example of an appropriate use of this authority.

Grants. Consistent with statutory authority, funds may be awarded by CBMS JPMO to stimulate or support a public purpose consistent with the broad CBMS JPMO objectives to develop, approve, and field medical CBRN countermeasures. These efforts should be intended for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding, rather than focusing on a specific system, product, or medical countermeasure. These grants are typically funded with Congressional special interest funds. By submitting a proposal and accepting an award, the recipient organization is certifying that the Project Manager and other investigators' credentials have been examined and verified to ensure that the investigators are qualified to conduct the proposed study, and if applicable, to use humans or animals as research subjects in accordance with all federal and institutional guidelines and regulations.

The type of instrument used to reflect the business relationship between the recipient and the U.S. Government will be determined by the Grants, Agreements, or Contracting Officer prior to award. The USASMDC, which provides contracting support to CBMS JPMO, will process proposals selected for funding.

## **2. Basic CBMS JPMO Award Procedures**

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The USASMDC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive federal awards. The EPLS is online at <http://www.epls.arnet.gov>. (Reference DoD Grant and Agreement Regulations [DoDGARs] section 25.110). Grants funds are generally awarded via cost-reimbursement or periodic scheduled payments, in accordance with the negotiated payment schedule included in the award document.

Recipient organizations should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities and conformance with safety and environmental statutes and regulations in accordance with DoDGARs section 22.410 or FAR subpart 9.1.

Investigators are cautioned that awards are made to organizations, not individuals. A Project Manager must submit a proposal through, and be employed by, an organization in order to receive support. (Federally Funded Research and Development Centers are not eligible for awards in accordance with FAR 35.017-7). **Should the Project Manager of a funded project leave the recipient institution, both the Project Manager and institution must contact USASMDC as soon as possible to discuss options for continued support of the project. Every effort should be made to notify USASMDC prior to the Project Manager leaving the institution.**

**Organizations located outside of the U.S. may submit in response to the BAA, however, it is the organizations' responsibility to ensure that the project staff is able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the United States. In addition, the U.S. Government will not provide funds to support scientists from countries which support terrorism.**

Funding may be provided incrementally during the life of the award. Under cost-reimbursement type awards, payments are made in response to monthly vouchers or invoices submitted by the awardee.

As to grants and procurement contracts, the primary basis for the selection of proposals is based upon evaluation of technical merit, programmatic relevance, and the availability of funds. Separate evaluation and selections criteria/procedure will exist for awards of prototype OT agreements announced under this BAA. Criteria and requirements for submission and evaluation of proposals may differ from those of other USASMDC solicitation instruments, as well as other requirements stated in this BAA. Such differences will be noted in the specific BAA Supplement or solicitation instrument. For example, these special programs usually specify a submission closing date, and a specific submission process. Other areas where differences may apply include the following:

1. Submission of preproposals of one page or longer may be required.
2. Submission of Letters of Intent may be required.
3. Full proposal submission requirements may be sent to the applicant with an invitation to submit a full proposal.
4. Progress reporting requirements may differ and will be detailed in the award document.
5. Points of contact for Project Manager inquiries may be identified.
6. Travel Cost guidelines may differ.
7. Project Manager notification of proposal receipt may differ.

Detailed information on proposal evaluation and selection is located in section III, "Evaluation and Selection."

#### B. CONFLICT OF INTEREST

There are certain post-employment restrictions on former Federal officers and employees as defined in 18 USC 207 and FAR 3.104-4(c). If a submitter believes a post-employment restriction or conflict of interest exists, the situation should be discussed with the CBMS JPMO legal staff (telephone 301-619-8444) prior to expending time and effort in preparation of a proposal.

#### C. DISCLOSURE OF INFORMATION OUTSIDE THE U.S. GOVERNMENT

Proposals may be disclosed outside of the U.S. Government subject matter experts for the sole purpose of technical and programmatic evaluation. The CBMS JPMO obtains a written agreement from the evaluators that information in the proposal will only be used for evaluation purposes and will not be further disclosed. Proposals for funded projects will be subject to public release under the Freedom of Information Act to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

#### D. U.S. GOVERNMENT OBLIGATION

Only a warranted Contracting, Grants, or Agreements Officer may obligate the U.S. Government to the expenditure of funds for awards under this BAA. The U.S. Government does not fund preparation of proposals or support work efforts or tasks that are inferred from discussions with technical project officers.

## E. INFORMATION SERVICE

Submitters may use the technical reference facilities of the Defense Technical Information Center (DTIC) to acquire information of U.S. Government funded projects to avoid duplication of scientific and engineering effort. The Defense Technical Information Center (DTIC) is responsible for collecting all scientific or technological observations, findings, recommendations, and results derived from Department of Defense endeavors. Requests for eligibility and registration information should be addressed to DTIC-BC Registration, 8725 John J. Kingman Road, Ft. Belvoir, VA 22060-6218, or may be obtained at <http://www.dtic.mil>.

## F. PREPROPOSALS

Organizations are strongly encouraged to explore CBMS JPMO interest by submitting a preliminary proposal (preproposal). Preproposals may be submitted at any time describing a specific idea or project that pertains to any of the advanced development areas of interest outlined in the BAA. **Preproposals should be no longer than three pages, and include a description of the relevant technology including supporting data, the scope of the proposed effort including a high-level Work Breakdown Structure (WBS), and a description of the proposer's research, development, manufacturing, past performance, or other special qualifications. The preproposal should include an anticipated cost for the efforts described in the preproposal.** Preproposals may be submitted to the following email address: [cbmsbaa@amedd.army.mil](mailto:cbmsbaa@amedd.army.mil). Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a preproposal. All preproposals will be assigned an identification number and an email or postcard will acknowledge receipt of a preproposal. Usually, the Project Manager should receive a decision letter or email regarding the preproposal within 60-90 days of submission.

## G. FULL PROPOSALS

If the preproposal for a procurement contract or Prototype OT is accepted, USASMDC/CBMS JPMO will send the Offeror (or Offerors in the event competitive Prototype OT proposals are received) a Request For Full Proposal (RFFP), upon acceptance of the full proposal, the offeror will be sent any additional requirements, including suggested Contract Line Item Numbers (CLINs), a Contract Data Requirements List (CDRL), clauses, terms, and conditions. Full proposals shall be submitted within 90 days after being requested. The U.S. Government reserves the right to reject submissions received more than 90 days after the request for a full proposal from the U.S. Government. Receipt of full proposals will be acknowledged by email or postcard. The Proposal Log Number for the full proposal will be the same number used for the preproposal (if one was submitted).

To apply for a grant, the forms identified for the CBMS JPMO BAA on the Grants.gov web portal must be completed and included as part of the submission for a full proposal. Full proposals may be submitted without protocols for human and animal use. However, protocols with required institutional approvals must be submitted not later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The contracting office may make exceptions in situations where human and/or animal use is not expected to begin until after

the first year of the award. In such cases, a time frame for submission of the appropriate protocols should be established during discussions/negotiations, prior to award.

There are no specified funding limitations identified for the proposals submitted under the CBMS JPMO BAA. The budget should be commensurate with the nature and complexity of the proposed effort. An award decision should be forwarded by the U.S. Government within 180 days after submission.

## **V. APPLICATION INSTRUCTIONS**

### **A. GENERAL FORMATTING GUIDELINES**

Applications for all types of awards under this BAA (grant, procurement contract, or Prototype OT) shall be clear and legible, and must conform to the following general formatting guidelines:

1. Elaborate proposals with high-gloss paper, vivid colors, detailed artwork, or other embellishments are unnecessary and not desired.
2. Paper: Pages shall be 8.5 x 11 inches, single sided, with each page numbered “X of Y pages.”
3. Margins: Minimum of 1 inch on all sides.
4. Type Font: 12 point Times New Roman, single spaced.
5. Contract Work Breakdown Structure (CWBS) and Integrated Master Schedule (IMS)/Gantt Charts: The minimum CWBS expected is Level 4. The IMS shall document the critical path and predecessor tasks.
6. Acronyms: Spell out all acronyms the first time they are used. One page of the proposal body is allocated to spell out acronyms, abbreviations and symbols.
7. Language: English.
8. Electronic file format: PDF, compatible with Adobe Acrobat Reader v. 8.0. File size less than 20 MB.

### **B. CONTRACTS AND PROTOTYPE OTS**

If a preproposal submitted in response to this BAA is accepted by the U.S. Government, a Request for Full Proposal (RFFP) will be sent to the organization submitting the preproposals (or organizations in the event competitive Prototype OT proposals are received). The following is general guidance as to the scope of the proposal for a contract or Prototype OT.

The Offeror’s proposal shall be submitted in one volume. Six paper copies, of which one is marked “Original” and the remainder “Copy” and an electronic copy of all proposal documents on CD-ROM shall be submitted to the address on page 3 of this BAA. The proposal shall

conform to the general formatting guidelines, above. The proposal shall include the following sections, which shall conform to the following page limits:

**1. Cover Page (1 page)**

- (a) BAA number
- (b) Lead Organization Submitting proposal
- (c) Type of business, selected among the following categories: “Large Business,” “Small Disadvantaged Business,” “Other Small Business,” “HBCU,” “MI,” “Other Educational,” or “Other Nonprofit”
- (d) Contractor’s reference number (if any)
- (e) Proposal Title
- (f) Technical point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail address (if available)
- (g) Administrative point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail address (if available)
- (h) Date proposal was prepared

## **2. Technical Section (20 pages)**

- a) Acronyms, Abbreviations, and Symbols
- b) Project objective. Describe what will be accomplished if the U.S. Government funds the proposal. Describe how it fulfils an area of interest described by this BAA.
- c) Background data. Include, for example, data supporting the safety and efficacy of the proposed technology, the validity of models used to test and evaluate the technology, and Offeror compliance with GLP, current Good Manufacturing Practices (cGMP), and/or Good Clinical Practices (GCP) compliance, as appropriate.
- d) Proposed technical approach. Describe in a comprehensive manner the technical approach proposed to accomplish the project objective. Describe the proposed technical approach in sufficient detail so that the U.S. Government may determine that the proposed approach is of acceptable risk.

## **3. Project Management Section (20 pages):**

- a) Statement of Work (SOW). The Offeror shall submit a SOW. The SOW shall describe the work to be performed by the Offeror (and any subcontractors). The final proposed SOW, when accepted by the U.S. Government, shall be incorporated into the contract or Prototype OT at the time of award. For this reason, the SOW shall be a stand-alone document.
- b) CWBS and CWBS dictionary. The offeror shall submit a CWBS and CWBS dictionary using MIL-HDBK-881 as a guide ([http://www.acq.osd.mil/pm/currentpolicy/wbs/MIL\\_HDBK-881A/MILHDBK881A/WebHelp3/MILHDBK881A.htm](http://www.acq.osd.mil/pm/currentpolicy/wbs/MIL_HDBK-881A/MILHDBK881A/WebHelp3/MILHDBK881A.htm)). The minimum CWBS expected is Level 4. However, the Offeror shall extend CWBS elements as needed to obtain the depth and breadth required to define the contract scope and to accurately describe the proposed effort. The CWBS shall correlate with the SOW and CLINs. The CWBS shall conform to instructions regarding font size.
- c) IMS. The IMS shall document the critical path, major milestones, tasks/activities, duration, lead/lag/slack time, and schedule relationships. The IMS shall be directly traceable to the SOW, CLINs, and the CWBS. The IMS is intended to be used as a tool for day to day tracking of the program/project. Tasks/activities should roll-up to increasingly higher summary levels. All tasks/activities in the IMS should be logically linked together showing predecessor/successor relationships. The tasks/activities shall be sufficient to account for the entire program/project under contract or Prototype OT. Dates delineated in the IMS and Section F shall become contractually binding, and will be adjusted accordingly, based on actual contract award date. At the Offeror's option, the IMS may be submitted on large format paper, no greater than 2 meters by 2 meters in size. This will not count against any page limit, other than as needed in the Project Management Section to reference the large-format IMS. The IMS shall conform to instructions regarding font size. The Offeror shall also submit an electronic copy of the schedule for submission of schedule data in "Read Only" format that shows all formulas and links for review. The data file shall be in the native format of the commercially off the shelf software .
- d) Project Management Approach. The approach to managing and integrating the various aspects of the required work shall be described in sufficient detail so that the U.S. Government

may assess associated risks. The Offeror shall identify significant milestones, decision points, and the processes that will be used to evaluate program status and progress. The Offeror shall include a description of any functional oversight. The Offeror shall present mechanisms for interactions/communications between Program Management and the U.S. Government, to include how processes will be updated (e.g., managing and interfacing with key Subcontractors and the U.S. Government). The Offeror shall include a description of management relationships or techniques that will be used to supplement day-to-day processes and procedures.

e) **Risk Management Plan.** The Offeror shall identify potential risks and describe the implementation of an integrated and proactive risk management plan as part of an overall management scheme (e.g., risk planning, risk assessment, risk handling, risk monitoring and documentation). The risk management plan shall discuss integrated methods for identifying, analyzing, prioritizing, and tracking risk drivers and include plans for adequate resources for risk mitigation. The Offeror shall describe tools or methodologies used in the integrated risk management and risk assessment processes.

#### **4. Past Performance Section (10 pages).**

The Offeror shall list ongoing and previous U.S. Government contracts held during the past three years, which are relevant and demonstrate ability to perform the effort required by the proposal. The Offeror shall explain the relevance of previous efforts with respect to the effort described in the proposal. If the Offeror has limited U.S. Government contracting experience, a description of similar contracts with commercial entities, local and/or state governments should be included, if relevant. Information furnished concerning these efforts shall be similar to that requested of U.S. Government contracts. The Government may send Past Performance questionnaires to Reference(s) listed. For that reason, the offeror must provide current contact information of all references listed in this section, to include: POC name, address, phone number, fax number and email address.

#### **5. Cost Section (40 pages)**

##### **a. Cost proposal**

The Cost Proposal shall be an integrated and comprehensive estimate with descriptions of estimating techniques and allocation methods that correlate in sufficient depth with the SOO, SOW, CWBS, IMS and CLINs when applicable. Estimating technique(s) used to create the proposal shall be clearly identified. Reasonable and supportable allocation techniques may be used to spread hours and/or cost to lower levels of the CWBS. While it is intended that Offerors shall use their own format for providing the information requested in these instructions, failure to submit all information requested may result in rejection of your proposal.

The Cost Proposal shall utilize a Microsoft Excel 2003-compatible spreadsheet for submission of cost or pricing information in “Read Only” format that shows all formulas and links for review. The cost proposal shall include a cost breakdown by CLIN and by U.S. Government Fiscal Year (1 Oct-30 Sep) of effort proposed. Offerors shall use a table similar to that shown below. Option CLINs and Subcontractor efforts shall be reflected separately, but will include at a minimum, the information requested in the spreadsheet below.

	FY08	FY09	FY10	FY11	FY12	Total
Direct Labor Hours						



Direct Labor Dollars						
Overhead						
Subcontractor 1						
Subcontractor 2						
Consultants						
Material and Supplies						
Material Handling						
Travel						
Equipment						
Other Costs						
SUBTOTAL: Direct Costs						
G&A						
FCCOM						
Total Estimated Target Cost						
Target Fee						
Total Target Cost and Fee						

(1) For Cost reimbursable-type CLINs only, the Offeror shall submit an estimate by CWBS, by U.S. Government Fiscal Year (FY) (1 Oct – 30 Sep). A sample table is shown below. Data for this spreadsheet will be provided at a minimum of CWBS Level 4 with subtotals provided at level 2.

CWBS Task Identification			Contractor	Fiscal Years			Total
CWBS Number	CWBS Level	Description		FY08	FY09	FY10	

The Offeror shall address the following cost elements in sufficient detail to demonstrate reasonableness of the proposed costs.

(2) Direct Labor. Provide estimated hours by CWBS (minimum Level 4), labor category and U.S. Government fiscal year. Indicate if the proposed loaded rates are based on actual or projected rates for current employees. Indicate the escalation factor used and first month(s) for each U.S. Government fiscal year which escalation factor is applied. Level of effort activities shall be expressed in man-hours. Define the number of man-hours that equal a man-year. A sample table is shown below.

CWBS	Contractor	Labor Category	FY08			FY09		
			Hours	Rate	Total	Hours	Rate	Total

(3) Subcontractor Costs. Provide a complete description of all Subcontractor costs by CWBS (minimum level 4). Submit Subcontractor proposals for estimates that exceed \$50,000. Provide price reasonableness for each Subcontractor proposal and explain how the cost was evaluated and determined to be fair and reasonable. A breakdown of all cost elements for each subcontractor must be provided regardless of estimated subcontract value.

(4) Consultants. Justify the requirement for consultant services. List proposed Consultants by name, if known. For each Consultant, describe: (1) nature of services, (2) CWBS supported (minimum Level 4), (3) fee rate, and (4) total Consultant fee and any other allowable related costs (e.g., travel, per diem).

(5) Materials and Supplies. Provide a detailed listing of materials and supplies by CWBS (minimum Level 4), quantity, unit cost, and basis of estimate (e.g., vendor quotes, catalog pricing, subcontracting estimates). Competitive historical price information of prior purchases is adequate. For all sole-sourced materials and supplies, provide a consolidated cost summary of individual material quantities included in the CWBS being proposed and the basis of estimate. A sample table is shown below.

Description	CWBS	Basis of Estimate	Quantity	Unit Cost	Source(s)

(6) Travel. Provide the purpose, origin, destination, and duration of travel. Offerors are encouraged to read FAR 31.205-46 regarding allowability of travel costs. A sample table is shown below.

CWBS	Dates	Origin/Destination	Purpose	No. of Persons	Airfare	Hotel	Per Diem	Rental Car	Total

(7) Equipment. Provide a list of all proposed equipment to be purchased in support of the contract by CWBS (minimum level 4). The list shall include equipment description, manufacturer, manufacturer's address, model and stock number, and estimated unit cost. A sample table is shown below.

Description	CWBS	Basis of Estimate	Quantity	Unit Cost	Purpose

(8) Other Costs. List direct costs not included in the above categories (i.e., special tooling, computer services, preservation, and packaging). Provide basis of estimate.

(9) Indirect Cost. Provide current DCAA approved rates for Overhead, Material Handling, General and Administrative (G&A), Facility Capital Cost of Money and any other indirect costs for all effort proposed. Provide forward pricing agreements if applicable. If forward pricing

agreements are not in place, include historical trend for the last three-year period to assist in evaluating proposed rates.

(10) Facilities Capital Cost of Money (FCCM). If FCCM is proposed, the Offeror must submit Form CASB-CMF and show the calculations of the proposed amount (see FAR 31.205-10).

(11) If the Offeror is currently under audit cognizance of Defense Contract Management Agency (DCMA) or Defense Contract Audit Agency (DCAA), the address and telephone number of the U.S. Government Agency's Point of Contact shall be furnished.

(12) Estimating System. Provide a description of the estimating system or methods used. Identify any deviations from these standard estimating procedures used in preparing this cost proposal. Indicate if there is U.S. Government approval of the system and if so, provide evidence of such approval.

(13) Purchasing System. Provide a summary description of the purchasing system or methods (how sources are selected, what provision is made to ensure quantity and other discounts) used. Identify any deviations from these standard procedures in preparing this cost proposal. Indicate if there is U.S. Government approval of the system and if so, provide evidence of such approval.

(14) Accounting System. Indicate if there is U.S. Government approval of the accounting system and if so, provide evidence of such approval. Identify any deviations from these standard procedures in preparing this cost proposal. Please note that to be eligible for a cost type contract, the offeror must have a DCAA acceptable accounting system. Please contact your cognizant DCAA for further information prior to submission of your proposal.

(15) Company Financial Statements. Offerors shall provide copies of their annual financial statements for the last three years.

(16) Representations, Certifications, and other Statements of Offerors. Representations & Certifications: Registration in Online Representations and Certifications Application (ORCA) is necessary for all organizations required to be registered with CCR. The form is located at <http://orca.bpn.gov>. ORCA is an E-Government initiative that was designed by the Integrated Acquisition Environment (IAE) to replace the paper based Representations and Certifications process.

(17) Security Requirements. Although not to be evaluated, the Offeror shall identify existing or describe capability of obtaining personnel/facilities security clearances.

## **5. Appendices (no page limit)**

- a) Key personnel qualifications
- b) Other documentation that may be requested by the U.S. Government in the RFFP.

## **C. GRANTS**

a) The Federal Financial Assistance Management Improvement Act of 1999, also known as P.L. 106-107, was enacted on November 20, 1999. The purposes of the Act are to (1) improve the effectiveness and performance of Federal financial assistance programs, (2) simplify Federal financial assistance application and reporting requirements, (3) improve the delivery of services to the public, and (4) facilitate greater coordination among those responsible for delivering services.

b) Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between grant applicants and the Federal agencies that manage grant funds. The grant community, including state, local and tribal governments, academia and research institutions, commercial firms and not-for-profits, can access the annual grant funds available across the Federal Government through one website, Grants.gov. In addition to simplifying the grant application process, Grants.gov also creates avenues for consolidation and best practices within each grant-making agency.

c) In compliance with P.L. 106-107, CBMS JPMO requires proposals submitted for a grant award in response to the BAA to be submitted through Grants.gov. This requires that organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual Project Managers DO NOT register; however, the Authorized Organizational Representative (AOR) is required to register. The registration process can take several weeks so please register as soon as possible. **For detailed instructions on electronic proposal submission using the Grants.gov portal, please refer to Appendix 1 attached to the end of this document.**

d) Organizations that submit a preproposal or “white paper” and are subsequently invited to submit a full proposal under the BAA, will be directed to submit through Grants.gov. Early planning with your organization will facilitate this process. Issues in submitting applications through the Grants.gov portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email [support@grants.gov](mailto:support@grants.gov). The Contact Center hours of operation are Monday-Friday, 7 AM to 9 PM Eastern Standard Time.

e) The following actions are required as part of the registration process. If you do business with the Federal Government on a continuing basis, it is likely you have already completed some of the actions, e.g., obtaining a Data Universal Number System (D-U-N-S®) Number or registration in Central Contractor Registry (CCR). Detailed information, automated tools, and checklists are available at [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp).

## **1. D-U-N-S® Number**

An organization will need a D-U-N-S® Number. A D-U-N-S® Number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B). If an organization does not have a D-U-N-S® Number, an authorized official of the organization can request one by calling 1-866-705-5711 Monday-Friday from 7 AM to 8 PM Central Standard Time or online via <http://fedgov.dnb.com/webform>. Organizations located outside of the United States, can request and register for a D-U-N-S® Number online via <http://fedgov.dnb.com/webform>.

## **2. CCR**

An organization must be registered with CCR before submitting a grant application through Grants.gov or receiving an award from the Federal Government. CCR validates applicant information and electronically shares the secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT).

You can register by calling the CCR Assistance Center at 1-888-227-2423 or register online at <http://www.ccr.gov>. If you have the necessary information, online registration will take about 30 minutes to complete, depending upon the size and complexity of your organization.

## **3. AOR**

Before submitting a proposal, an organization representative needs to register to submit on behalf of the organization at Grants.gov - [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp). An organization's E-Business Point of Contact (POC), identified during CCR Registration, must authorize someone to become an AOR. This safeguards the organization from individuals who may attempt to submit proposals without permission. **Note:** In some organizations, a person may serve as both an E-Business POC and an AOR.

An AOR must first register with the Grants.gov Credential Provider at [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp) and then with Grants.gov. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Business POC for assignment of user privileges. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email.

## **4. Full Proposal Preparation for Grants**

### **a) Mandatory Grant Proposal Forms and Attachments.**

A complete proposal package includes all required forms and attachments completed, including the full project proposal. The definitive list of required forms is identified at <http://www.grants.gov/> and includes:

1. Standard Form (SF) 424 (Research and Related [R&R]) Application for Federal Assistance.
2. R&R Budget.
3. R&R Subaward Budget Attachment(s) Form (if needed).
4. R&R Project/Performance Site Location(s).
5. R&R Senior/Key Person Profile.
6. R&R Other Project Information.

These forms are available from the Grants.gov web site:  
[http://www.grants.gov/agencies/aapproved\\_standard\\_forms.jsp#2](http://www.grants.gov/agencies/aapproved_standard_forms.jsp#2).

The required attachments are:

1. Budget Justification for entire performance period
2. Project Manager Biographical Sketch
3. Project Manager Current/Pending Support
4. Key Personnel Biographical Sketches
5. Key Personnel Current/Pending Support
6. Proposal Abstract
7. Project Narrative and Body of Proposal
8. Certificate of Environmental Compliance
9. Facility Safety Plan
10. Representations and Certifications
11. Individual subaward budgets

Additional information, such as templates, is available on the Grants.gov web portal and the JPEO-CBD web site.

NOTE: All Attachments that require signatures must be filled out electronically, printed, signed, scanned, and then uploaded as an Attachment to the proposal as a PDF file.

b) Instructions for Mandatory Grants Proposal Forms

(1) SF 424 (R&R), Application for Federal Assistance

This form is required for each application. The form is self-explanatory, with the following exceptions:

1. The Applicant Identifier box should be filled in with the unique Proposal Log Number, if one has been assigned.
2. Block 4 - Federal box should be used to identify the Funding Opportunity or an award number.

(2) R&R Budget

An estimate of the total project cost, with a breakdown by category and year (using the Federal Government's FY calendar), must accompany each full proposal. All costs must be entered in U.S. dollars. Recipients performing outside of the U.S. should include the cost in local currency, the rate used for converting to U.S. dollars and justification/basis for the conversion rate used. Multiple year proposals are strongly encouraged to cover the total estimated duration of the project. Incremental funds may be provided by the CBMS JPMO for effort performed during each Federal FY. Costs proposed must conform to the following regulations and principles:

1. Commercial Firms: FAR Part 31 and Defense FAR Supplement (DFARS) Part 31, (<http://farsite.hill.af.mil>) Cost Principles and Procedures.
2. Educational Institutions: 2 Code of Federal Regulations (CFR) Part 220 (formerly U.S. Office of Management and Budget [OMB] Circular A-21), Cost Principles for Educational Institutions.
3. Nonprofit Organizations: 2 CFR Part 230 (formerly OMB Circular A-122), Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations.

The cost of preparing proposals in response to this BAA is not considered an allowable direct charge to any resultant grant. It is, however, an allowable expense to the bid and propose indirect costs specified in FAR 31.205-18, 2 CFR 220, 2 CFR 230 and OMB Circulars A-21 and A-122, as appropriate.

Section A & B – Senior/Key Personnel: The basis for labor costs should be predicated upon actual labor rates or salaries. Budget estimates may be adjusted upward to forecast salary or wage cost-of-living increases that will occur during the period-of-performance. The proposal should separately identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases.

The qualifications of the Project Manager and the amount of time that they and other professional personnel will devote to the project are important factors in evaluating proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

Section C – Equipment Description: An itemized list of permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than two years and an acquisition cost of \$5,000 or more per unit. The justification for the cost of each item of equipment included in the budget must be disclosed to include:

1. Vendor Quote: Show the name of the vendor and number of quotes received and justification if intended award is to other than the lowest bidder.
2. Historical Cost: Identify the vendor, date of purchase and whether or not the cost represented the lowest bid. Include release(s) for not soliciting current quotes.
3. Estimate: Include a rationale for the estimate and reasons for not soliciting current quotes.
4. Special equipment to be fabricated for specific purposes and its cost.
5. Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs, listing separately.
6. Existing equipment to be modified to meet specific requirements, including modification costs. Do not include as special test equipment those items of

equipment that, if purchased by the Contractor with Contractor funds, would be capitalized for federal income tax purposes.

When Grants are awarded, the title to equipment or other tangible property purchased with U.S. Government funds may be vested in institutions of higher education or nonprofit organizations, if it will facilitate other efforts performed by the institution or organization for the U.S. Government.

Section D – Travel: The justification supporting travel costs should list the number of trips, number of people per trip, the destinations and the purpose for all proposed travel annually. Estimate round trip fare and per diem costs for each trip. Travel to scientific meetings requires identification of the specific meeting and purpose. The number of trips funded for scientific meeting is limited.

Section E – Participant/Trainee Support Costs: This section is self-explanatory.

Section F – Other Direct Costs:

Section F.1 – Materials and Supplies (Consumables): The justification supporting materials and supplies (consumable) costs should include a general description of expendable equipment and supplies. If animals are to be purchased, state the species, strain (if applicable) and the number to be used. If human cell lines are to be purchased, state the source and the description.

Section F.2 – Publication Costs: This section is self-explanatory.

Section F.3 – Consultant Services: Regardless of whether funds are requested, the justification should include the names and organizational affiliations of all consultants. State the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed project.

Section F.4 – ADP/Computer Services: This section is self-explanatory.

Section F.5 – Subaward/Consortium/Contractual Costs: The cost justification must include a description of services or materials that are to be awarded by subcontract or sub grant. The following information must be provided on subawards totaling \$10,000 or more:

1. Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
2. Identification of the proposed Subcontractor or sub grantee, if known, and an explanation of why and how the Subcontractor or sub grantee was selected or will be selected;
3. Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and the proposed acquisition price.
4. The Offeror's cost or price analysis for the sub grant or subcontract proposed price (applicable only if the award exceeds \$500,000).

If the resultant award is a contract that exceeds \$500,000 and the offeror is a large business or an educational institution (other than Historically Black Colleges and Universities & other Minority



Institutions Program (HBCU/MI)), the Contractor is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

Section F.6 – Equipment or Facility Rental/User Fees: This section is self-explanatory.

Section F.7 – Alterations and Renovations: This section is self-explanatory.

Section F (8 – 10) – Research-Related Subject Costs: Include Itemized costs of subject participation in the clinical study. These costs are strictly limited to expenses specifically associated with the proposed study. The CBMS JPMO will not provide funds for ongoing medical care costs that are not related to a subject's participation in the clinical study.

Section F (8 – 10) – Other Direct Cost: Include other anticipated direct costs that are not specified elsewhere in the budget. Unusual or expensive items should be fully explained and justified.

Section G. – Direct Costs: This section is self-explanatory.

Section H – Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s) and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed. If negotiated forecast rates do not exist, provide sufficient detail regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or part of 2 CFR (see above). Commercial firms can also visit <http://www.dcaa.mil> for additional information on indirect rates. Universities may obtain additional information from the Office of Naval Research web site (<http://www.onr.navy.mil/02/rd.asp?nm=uba>). Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established.

As a minimum, justification for indirect costs should identify:

1. All individual cost elements included in the forecast rate(s);
2. The basis used to prorate indirect expenses to cost pools, if any;
3. How the rate(s) was calculated; and
4. The distribution basis of the developed rate(s).

Section I – Total Direct and Indirect Costs: This section is self-explanatory.

Section J – Fee: Profit or fee is not allowable on grants. If a profit or fee is negotiated, a contract or Prototype OT will be awarded. Any fixed fee applied to the Advanced Development Project must be listed and any claimed Facilities Capital Cost of Money supported by DD Form 1861 (<http://www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfo2192.html>) submitted with the full proposal.

Section K. – Budget Justification: The Budget Justification must be included as an attachment at R&R Budget – Section K for each FY period. Organizations must provide sufficient detail and justification so that the U.S. Government can determine the proposed costs to be allocable and

reasonable for the proposed effort. Attach one file that addresses each of the cost elements proposed. All entities submitting a proposal should also submit notice of rate evaluation by the DCAA or the Forward Pricing Agreement for rates if one exists.

(3) R&R Project/Performance Site Location(s)

Include the names and addresses for each location where proposed work will be performed.

(4) R&R Senior/Key Person Profile

Include the requested information for each senior/key person proposed on the project and attach 1) a current biographical sketch (Attachment 1, located at <http://www.grants.gov/>) and 2) current & pending support on which this person is working or proposed. The list of Current/Pending Support should be attached in MS Word format and should include the title, time commitments, supporting agency and level of funding for all existing and pending projects involving the Project Manager and key personnel. Provide justification for CBMS JPMO support and interest where the projects overlap or parallel. In order to enable a proper determination of the Offeror's past performance, either for use in a technical evaluation or for determination of the necessary level of preaward survey, it is requested that synopsis of awards be prepared on similar or related effort for the past three years, including:

1. Specifics on each award, including types and dates of performance.
2. The name and address of the Procuring Contracting/Grants Officer.
3. The negotiated price, and the final cost to the U.S. Government, with reasons for the variance.

(5) R&R Other Project Information

This form is self-explanatory. The following information must be included as attachments to this form:

Blocks 1 - 5: This section is self-explanatory in addressing the use of human subjects, the use of animals, proprietary information and environmental impact of the proposed work effort.

Block 6. – Project Summary/Abstract: The abstract is vitally important to both the peer and programmatic review process. The programmatic review includes an evaluation of the abstract as part of the peer review summary statement; therefore, it is paramount that the Project Manager submits an abstract that fully describes the proposed work. The abstract must contain the title of the proposal and the name of the Project Manager. Do not include figures or tables in the abstract. Spell out all Greek or other non-English letters. Abstracts of all funded proposals may be posted; therefore, proprietary or confidential information should not be included in the abstract.

The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale, significance of the proposed work to the program's goals, specific aims of the study and the study design. It shall be no longer than one page.

An outline is provided below for preparing the structured technical abstract.

1. Background: Provide a brief statement of the ideas and reasoning behind the proposed work.
2. Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
3. Specific Aims: State concisely the specific aims of the study.
4. Study Design: Briefly describe the study design.
5. Relevance: Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on medical CBRN countermeasures advanced development outcomes.

Block 7 – Project Narrative (limit 25 pages): The Project Narrative includes the SOW and the body of the proposal, in that order. There is no form for this information. The attachments should be in MS Word, MS Project, and/or PDF format in accordance with the formatting guidelines specified for full proposal preparation.

The SOW outlines and establishes the proposed performance expectations for which CBMS JPMO may provide funding. If a FAR based contract is awarded, the SOW is incorporated into Section C of the contract and becomes binding. The Contractor is expected to meet the provisions and milestones of the SOW. The SOW is incorporated into the award document and, as such, may be subject to release under The Freedom of Information Act [FOIA]. The SOW should be from one to five pages in length, depending on the scope and nature of the work proposed.

A series of relatively short statements should be included which comprise the approach to each of the major goals or objectives of the proposed effort. The statements should outline the specific tasks, systems and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included which shows the work statements to be accomplished in each year of the award.

**BODY OF PROPOSAL** - A detailed description of the effort to be undertaken shall be submitted. This includes background, hypothesis, objectives, approach, methods, and their relationship to the state of knowledge in the field and to comparable work in progress elsewhere. This information shall not exceed 20 pages, shall be formatted as described above, and submitted in PDF format. Evaluation of the proposed effort will be influenced substantially by the adequacy of this information. Literature references and curriculum vitae will be attached separately. The following general outline should be followed:

1. Background. Provide a brief statement of ideas and reasoning behind the proposed study. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
2. Technical Objectives. State concisely the specific objectives of each work element of the project. Each objective shall be a discreet grouping of tasks to accomplish a

specific goal. An example of an objective is a GLP-compliant mouse toxicity study. Include a Level 4 CWBS.

3. **Project Schedule and Milestones.** Identify time-lines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule and performance. Provide a high-level graphical Gantt chart of the project, showing predecessor relationships, and highlighting the critical path. The schedule and milestone shall correspond to the Technical Objectives.
4. **Military Significance.** Describe how the proposal supports the development of medical CBRN countermeasures, to include Countermeasure Prototypes, Special Projects, and Developmental Initiatives Supporting Medical CBRN Countermeasures and Enabling Technologies, as described in the “Areas of Interest” portion of this BAA and subsequent amendments. Also describe how the proposal supports other U.S. Government requirements, including other DoD requirements and the medical CBRN Medical Countermeasure development efforts of the Department of Health and Human Services, the Department of Veterans Affairs, or the Department of Homeland Security.
5. **Public Purpose.** Provide a concise description of how this project will benefit the public. Awards made by the DoD must benefit the public purpose of National Security.
6. **Technical Approach.** Describe in detail the proposed technical approach and methodology. If the methodology is new or unusual, describe in sufficient detail for evaluation. The approach should correspond to and reference the Technical Objectives and the Project Schedule and Milestones.

**Block 8 – Bibliography & References Cited:** List the references in the order they appear in the proposal narrative. Use a reference format, which gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF format, in accordance with the formatting guidelines specified for full proposal preparation.

**Block 9 – Facilities & Other Resources:** Describe the facilities available for performance of the proposed request and any additional facilities or equipment proposed for acquisition at no cost to the CBMS JPMO. Indicate if U.S. Government-owned facility or equipment is proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information. The attachments should be in PDF Format, in accordance with the formatting guidelines outlined for full proposal preparation.

**Block 10 – Equipment:** Include a description of existing equipment to be used for the proposed work effort. There is no form for this information. The attachments should be in PDF format, in accordance with the formatting guidelines outlined for full proposal preparation.

**Block 11 – Other Attachments:** Include other items appropriate to the proposal, such as:

1. **Acronyms and Symbol Definitions.** Provide a glossary of acronyms and symbols.

2. Collaboration, Consortia, and Joint Sponsorship. Provide letter(s) and/or charter(s) supporting stated collaborative efforts and consortia.
3. Certificate of Environmental Compliance. Information regarding environmental compliance must be provided with the full proposal.
4. Research Involving Human Subjects and/or Anatomical Substances. Awards funded by the CBMS JPMO require a second tier review for the use of human subjects, the use of human data, and the use of human anatomical substances prior to implementation. Therefore, the proposal must address all pertinent issues relating to the use of human subjects in the proposed project. Include the required approvals, forms and information as specified on the Human Research Protection Office (HRPO) website: <https://mrhc.amedd.army.mil/rodorphrpo.asp>. Full proposals may be submitted without protocols for human use. However, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of payments. The contracting office may grant exceptions in situations where human use is not expected to occur until after the first year of the project. In such cases, a time frame for submission of the appropriate protocols should be established during discussion/negotiations.
5. Research Involving Animals. Awards funded by the CBMS JPMO require a second tier review for the use of animals prior to implementation. Therefore, the Project Manager must address all pertinent issues relating to the use of animals in the proposed work effort. Include the required assurances, approvals, forms and description in the proposal addenda entitled "Research Involving Animals," as specified on the Animal Care and Use Review Office (ACURO) website <https://mrhc.amedd.army.mil/rodorpaurd.asp>. Projects performed under CBMS JPMO sponsorship that generate preclinical safety data intended to support a research or marketing permit for products regulated by the FDA must be in conformance with GLP. Full proposals may be submitted without protocols for animal use; however, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of payments. The contracting office may grant exceptions in situations where animal use is not expected to occur until after the first year of the project. In such cases, a time frame for submission of the appropriate protocols should be established during discussion/negotiations.
6. Facility Safety Plan. The facility safety plan must be completed and included in the full proposal.

Representations & Certifications: Registration in Online Representations and Certifications Application (ORCA) is necessary for all organizations required to be registered with CCR. The form is located at <http://orca.bpn.gov>. ORCA is an E-Government initiative that was designed by the Integrated Acquisition Environment (IAE) to replace the paper based Representations and Certifications process.

Certifications and Assurances for Assistance Agreements: By signing and submitting a proposal or accepting an award, the recipient is concurring with the specified assurances and certifications, in compliance with the DoD Grants and Agreements Regulations, Part 22 and Appendices A and B.

The contracting/grants office may contact Offerors whose proposals are selected for funding for specific certifications and statements required by federal statutes and regulations. Failure to include all required information and completed forms with submission of the full proposal could delay the award process.

Other. Include in this section, any other documentation not specified elsewhere, that supports the proposal and could influence the evaluation and selection process.

(6) R&R Subaward Budget Attachment(s) Form

On this form, attach the subaward budget file for the application. Complete the subawardee budget(s) in accordance with the instructions. Please note that the files to be attached must be a Pure Edge Document.

The chart on the following page details the forms that should be submitted and their accompanying attachments.

Table 1

<u>Form</u>	<u>Attachment</u>	<u>Action</u>
<u>SF-424 (R&amp;R) Application for Federal Assistance Form</u>		<u>Enter the appropriate information in data fields</u>
<u>R&amp;R Budget Form</u>	<u>Budget Justification for entire performance period</u>	<u>Attach to Section K in budget period one</u>
<u>R&amp;R Project/Performance Site Location(s) Form</u>		<u>Enter the appropriate information in data fields</u>
<u>R&amp;R Senior/Key Person Profile Form</u>	<u>Project Manager Biographical Sketch</u>	<u>Attach to Biographical Sketch field</u>
	<u>Project Manager Current/Pending Support</u>	<u>Attach to Current &amp; Pending Support field</u>
	<u>Key Personnel Biographical Sketches</u>	<u>Attach to Biographical Sketch field for each senior/key person</u>
	<u>Key Personnel Current/Pending Support</u>	<u>Attach to Current &amp; Pending Support field for each senior/key person</u>
<u>R&amp;R Other Project Information</u>	<u>Proposal Abstract</u>	<u>Attach to Block 6</u> <u>Project Summary/Abstract</u>
	<u>Project Narrative and Body of Proposal</u>	<u>Attach to Block 7</u> <u>Project Narrative</u>

<u>Form</u>	<u>Attachment</u>	<u>Action</u>
	<u>Certificate of Environmental Compliance</u>	<u>Attach to Block 11</u> <u>Other Attachments</u>
	<u>Facility Safety Plan</u>	<u>Attach to Block 11</u> <u>Other Attachments</u>
	<u>Representations and Certifications</u>	<u>Attach to Block 11</u> <u>Other Attachments</u>
<u>R&amp;R Subaward Budget Attachment(s) Form (if applicable)</u>	<u>Individual subaward budgets</u>	<u>Attach a separate budget with justification for each subaward</u>

#### D. REGULATIONS AND FORMS

1. The CFR is available at <http://www.gpoaccess.gov/cfr>.
2. The FAR and DFARS are available at website <http://farsite.hill.af.mil>.
3. DoDGARs, DoD 3210.6-R are available at <http://www.dtic.mil/whs/directives/corres/html/32106r.htm>.
4. OMB Circulars are available at <http://www.whitehouse.gov/omb/circulars/index.html>.
5. Application forms are available at [http://www.grants.gov/agencies/aapproved\\_standard\\_forms.jsp#2](http://www.grants.gov/agencies/aapproved_standard_forms.jsp#2).
6. Representations & Certifications for organizations required to be registered with CCR are available at <http://orca.bpn.gov>.
7. Additional information on attachments is available at the Grants.gov web portal and the JPEO-CBD web site.

## VI. EVALUATION AND SELECTION

#### A. EVALUATION FACTORS FOR PROCUREMENT CONTRACTS AND GRANTS

Proposals will be evaluated in accordance with the competition requirements of FAR 35.016 (d) and (e), or 10 USC 2361, 10 USC 2371, 10 USC 2374, or DoDGARs 3210.6-R as appropriate. Specifically:

Proposals received as a result of the BAA shall be evaluated in accordance with evaluation criteria specified therein through a peer or scientific review process. Written evaluation reports on individual proposals will be necessary but proposals need not be evaluated against each other since they are not submitted in accordance with a common work statement.

The primary basis for selecting proposals for acceptance shall be technical, importance to agency programs, and fund availability. Cost realism and reasonableness shall also be considered to the extent appropriate.

Full proposals will be evaluated by CBMS JPMO scientists, other Federal Agency Representatives, outside scientists with diverse expertise, clinicians, consumers, or combinations thereof will evaluate proposals and assign scores based on the following factors (in descending order of importance):

1. Technical Merit: The proposed plans, methods, techniques, and procedures must be feasible, clear, valid, adequately referenced, and state-of-the-art. The proposed schedule must be reasonable. Literature searches are recommended for documenting the strengths of the proposed project.
2. Military and Program Relevance: Projects must support the development of medical CBRN countermeasures, to include Countermeasure Prototypes, Special Projects, and Developmental Initiatives Supporting Medical CBRN Countermeasures and Enabling Technologies, as described in the “Areas of Interest” portion of this BAA and subsequent amendments. Proposals should address an outstanding requirement and balance or reduce programmatic risk of the current CBMS JPMO medical CBRN countermeasure development program. Explain how the results of this project are expected to impact the intended beneficiaries.
3. Funds Availability: CBMS JPMO must have funds available to support the proposed work.
4. Technology Readiness Level (TRL): CBMS JPMO does not fund basic, applied, or advanced research. The technology proposed must meet TRL 3, and should meet TRL 4 or greater. For example, TRL 4 requires completion of non-GLP animal studies to assess the safety and efficacy of a candidate medical CBRN countermeasure. See the Areas of Interest for a full description of TRLs.
5. Project Objectives: The stated objectives must be clear, valid and logical. Projects that demonstrate an innovative approach are desired.
6. Regulatory compliance. The proposal will be evaluated for compliance with FDA guidelines for current cGMP, GLP, and GCP.
7. Support of other U.S. Government requirements. The proposal will be evaluated for alignment with other DoD requirements and the medical CBRN Medical Countermeasure development efforts of the Department of Health and Human Services, the Department of Veterans Affairs, or the Department of Homeland Security.



8. Key Personnel Qualifications: Document the qualifications, capabilities and experience of the proposed Project Manager and other key personnel in sufficient details to demonstrate that the proposed staff has the knowledge and skills to achieve the proposed objectives.
9. Facilities: Describe the proposed facilities and equipment, or unique combinations of these, in detail to demonstrate that the organization has the necessary facilities required for the accomplishing the proposed objectives.
10. Budget/Cost: The budget must reflect the actual needs of the proposed work and be fully justified so that the U.S. Government can evaluate and determine the cost to be fair and reasonable and commensurate with the complexity and nature of the work proposed. Where applicable, comparative cost will be employed as determined by CBMS JPMO in its discretion.
11. Past Performance: Documented satisfactory performance record. In the case of an offeror without a record of relevant past performance or for whom information on past performance is not available, the offeror may not be evaluated favorably or unfavorably on past performance.

## B. SELECTION FOR PROCUREMENT CONTRACTS AND GRANTS

Any proposal received may be negotiated. After the CBMS JPMO evaluation, proposals recommended for funding will be prioritized. A prioritized listing of alternates may also be prepared when warranted. Subsequent awards depend upon the availability of funds and fulfillment of requirements and priorities determined to exist at the time of award. In some cases, funding priorities may change as certain scientific tasks are addressed and new mission assignments arise. Award may also be dependent upon demonstration by the applicant that they have adequately addressed the following requirements, if applicable to the efforts being proposed:

1. Research involving Human Subjects/Anatomical Substances (if proposed).
2. Research involving Animals (if proposed).
3. Facility Safety Plan.
4. Certificate of Environmental Compliance.
5. Evidence of GLP Compliance (if appropriate).
6. Evidence of cGMP Compliance (if appropriate).
7. Evidence of GCP Compliance (if appropriate).
8. All required Representations and Certifications are completed and on file.

## C. EVALUATION AND SELECTION FOR PROTOTYPE OT AWARDS

### **Evaluation**

For each acquisition to be made using a Prototype OT, a specific RFP may be released to all interested parties. This will maximize competition and ensure consistent evaluation of all proposals. The RFP will specify, in Section M, the specific evaluation factors to be used in the evaluation of all proposals received in response to the solicitation.

## **VII. AWARD ADMINISTRATION**

### A. PAYMENT

#### **1. Contracts and Prototype OTs**

In accordance with DFARS Clause 252.232-7003, Electronic Submission of Payment Requests, the contractor shall submit invoices electronically. Invoices shall be made using the DoD's Wide Area Workflow (WAWF) system, Web Invoicing System, or system acceptable to the contracting or agreements officer. Information about WAWF can be found at <https://wawf.eb.mil/>. Contractors must be able to electronically receive payment funds.

#### **2. Grants**

Recipients of cost-reimbursable grants must request payment using SF 270. Grants may also include scheduled payments if warranted. Grant recipients must be able to electronically receive funds in accordance with DoDGARs 22.810.

### B. INFORMATION RELEASE

CBMS JPMO must approve the release of information pertaining to projects funded by CBMS JPMO. Approval must be sought through the cognizant Contracting, Grants, or Agreements Officer. Statement 1 shall be included in all such information releases; Statements 2-6 shall be included if relevant to the work being conducted.

1. "This work was supported by the Chemical Biological Medical Systems Joint Project Management Office under U.S. Army Space and Missile Defense Command Award No. \_\_\_\_\_. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army."
2. In conducting research using humans and/or human anatomical substances, the investigator is required to include approvals, forms and information specified on the HRPO website: <https://mrmc.detrick.army.mil/rodorppolicies.asp#USRegs>.
3. "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, forms and information specified on the ACURO website <https://mrmc.detrick.army.mil/rodorpaurd.asp>.

4. "In the conduct of research utilizing recombinant DNA, the investigator adhered to National Institutes of Health (NIH) Guidelines for research involving recombinant DNA molecules." (<http://www.nih.gov>)
5. "In the conduct of research involving hazardous organisms, the investigator adhered to the Centers for Disease Control (CDC)-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (<http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>)
6. "Information" includes, but is not limited to, news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and presentations or posters at scientific conferences, workshops, and symposia.

#### C. FREEDOM OF INFORMATION ACT REQUESTS

The FOIA (5 USC 552) provides a statutory basis for public access to official U.S. Government records. "Records" are defined to include documentation received by the U.S. Government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act (<http://www.usdoj.gov/04foia>).

When a FOIA request asks for information contained in a successful proposal that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USASMDC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USASMDC's intent to release and will be provided a reasonable opportunity to assert available action.

#### D. SITE VISITS

CBMS JPMO personnel may visit the award recipients during the project. All visits shall be coordinated with the cognizant Contracting, Grants, or Agreements Officer and are intended for technical discussion and monitoring of progress of the funded project.

#### E. REPORTS/MEETINGS/KNOWLEDGE DISEMINATION

Reports are necessary for continuation of funding. Reporting requirements are determined by the Contracting, Grants, or Agreements officer and reflect the type of award (grant, procurement contract, or OT for prototypes; firm fixed price or cost-reimbursable). Each request for full proposal will state the necessary reports that will be required. The Offeror must price all reports and deliverables. Reporting requirements may include the following:

1. Monthly or quarterly reports that outline the accomplishments and progress for that period.

2. Quarterly In-Process Reviews to discuss findings, accomplishments and direction for the program.
3. SF 272, Federal Cash Transaction Report, filed quarterly when grants with scheduled payments are made.
4. SF 269, Financial Status Report. Required for grants either annually or at project termination.
5. Annual reports that consist of detailed summaries of scientific issues, accomplishments and animal research usage during the project.
6. Final report that details the findings and issues of the completed project.
7. Disclosure of subject inventions in accordance with 37 CFR 401 using DD Form 882.
8. Copies of all scientific publications as a result of funding.
9. Abstracts suitable for publication in relation to planned meetings.
10. A Program Review shall be held annually at the Government's site in which the Recipient will be required to provide briefing charts and an oral presentation on their efforts achieved as a result of Government awarded funding.
11. Annual Publications:  
Recipient shall provide a 2-4 page narrative document of project accomplishments in a suitable format for inclusion in a non-peer reviewed publication. Examples of such publications include Chem-Bio Defense Quarterly, National Defense, CBRNe World, Defense AT&L, and others.

## F. AUDITS AND COST PRINCIPLES

Organizations receiving grants and cost-reimbursable contracts and Prototype OTs must be audited. See below for the governing cost principles for each award/business type.

### 1. Cost-Reimbursable Contracts and Prototype OTs

The Contractor's accounting system must be approved by the cognizant Administrative Contracting Officer (ACO). The following cost principles apply:

Organization	Type	Cost Principles
Educational Institutions		FAR 31.3
Nonprofit institutions		FAR 31.7
For-profit institutions		FAR 31.2 and DFARS part 231

## 2. Grants

Recipients are to periodically have independent financial and compliance audits subject to DoDGARs 32.26. The following cost principles apply:

<b>Organization Type</b>	<b>Cost Principles</b>
Educational Institutions	2 CFR Part 220 (formerly OMB Circular A-21)
Nonprofit institutions	2 CFR Part 230 (formerly OMB Circular A-122)
For-profit institutions	FAR part 31 and DFARS part 231

## APPENDIX 1. ELECTRONIC PROPOSAL SUBMISSION THROUGH THE GRANTS.GOV PORTAL

Prospective applicants will need to complete the following actions in order to participate in the Grants.Gov application process. It cannot be emphasized how important it is to START EARLY since it may take up to 14 days to get through all of the steps.

### 1. Registration

Each organization that desires to submit a proposal via Grants.Gov must complete the one-time registration (all steps) at <http://www.grants.gov/GetStarted>. To prepare for this process, you will need to do the following steps:

- a) Request a DUNS Number – Follow the instructions at: <http://www.grants.gov/RequestaDUNS> to obtain a DUNS number. It is highly recommended that you request the number by telephone at 1-866-705-5711. This will take about 10 minutes to complete and there is no charge. NOTE: Once the telephone registration is completed, you must call 24 hours before attempting to use that DUNS for registration in the Central Contractor Registry (CCR).
- b) Register in the Central Contractor Registry (CCR) – Go to <http://www.grants.gov/CCRRegister> and click on the “Help” button to locate the tutorial. It is recommended that you print the tutorial for reference and follow the instructions in the link above. It is also recommended that you print and complete the 7-page CCR Worksheet at <http://www.ccr.gov/CCRRegTemplate.pdf> prior to registration, as it may take up to 3 days to gather the information needed for the worksheet. You are required to designate an Electronic Business Point of Contact (E-Business POC) and a Marketing Partner Identification Number (MPIN) in CCR. It is important to provide the MPIN to the E-Business POC. For assistance with the CCR, contact the Assistance Center at 1-888-227-2423 or at [CCR@dlis.dla.mil](mailto:CCR@dlis.dla.mil). You may also access the CCR Handbook at <http://www.ccr.gov/handbook.asp>. **VERY IMPORTANT: Knowing the MPIN and who is designated as your organization’s E-Business POC in the CCR is a significant step in the process. This person will function as the organizational agent to approve personnel who can submit binding proposals on behalf of your organization.**
- c) Install the PureEdge Viewer – Authorized Organizational Representatives (AORs) approved by the E-Business POC are the individuals that will be given the authority to submit proposals on behalf of your organization. All AORs must download and install the PureEdge Viewer on their computer workstation by following the instructions at: <http://www.grants.gov/DownloadViewer>. This small, free program will allow AORs to access, complete, and submit applications electronically and securely. Should you encounter any problems, contact customer support at 1-800-518-4726 or [support@grants.gov](mailto:support@grants.gov).
- d) Register with the Credential Provider – AORs must register with the Credential Provider. AORs must wait a minimum of 3 business days for the CCR to activate the organization’s account before attempting to register with the Credential Provider at: <http://www.grants.gov/CredentialProvider> and click on the “Help” button to locate the tutorial.

Print the tutorial for reference and follow the instructions in the link above. Record the user ID and the password that you enter because you will need this information to register with Grants.gov as an AOR. AORs must wait approximately 20 minutes after completing the Credential Provider registration before going to the next step of registering with Grants.Gov. If you encounter any problems, the Credential Provider may be reached at 1-800-386-6820 or via email at [eauthhelp@arc.com](mailto:eauthhelp@arc.com) or [pkihelp@orc.com](mailto:pkihelp@orc.com).

e) Register with Grants.Gov – AORs must register with Grants.Gov, utilizing their User ID and Password obtained from registering with the Credential Provider. Go to [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp) and click on the “Help” button to locate the tutorial for reference and follow the instructions in the link above. After you have completed the Grants.Gov registration process, you will receive a confirmation that indicates whether your registration was successful. After an AOR successfully registers with Grants.Gov, an email will be generated to your organization’s E-Business POC to notify them that an individual has registered in Grants.Gov to be an AOR capable of submitting applications in Grants.Gov on behalf of your organization. AORs will not be able to submit electronic applications until they receive authorization from the E-Business POC. Normally, the E-Business POC should process these requests within 1 Business Day. If you encounter any problems, please contact customer support at 1-800-518-4726 or [support@Grants.Gov](mailto:support@Grants.Gov).

f) Designation of Privileges to the AOR – The E-Business POC is the sole authority of the organization with the capability of designating or revoking an individual’s ability to submit grant applications on behalf of their organization through Grants.Gov. Once the E-Business POC receives the email notification from the individual wishing to be recognized as an AOR, the E-Business POC should go to: <https://apply.grants.gov/AorMgrGetID> and click on the “Help” button to locate the tutorial, then log into the system using the DUNS number and Marketing Partner Identification Number (MPIN) designated for their organization when CCR registration was performed. Once in the system the E-Business POC should follow the instructions for designating privileges to the AOR. If the E-Business POC cannot locate the CCR MPIN, contact the CCR Assistance Center at 1-888-227-2423 or at [CCR@dlis.dla.mil](mailto:CCR@dlis.dla.mil).

## **2. Submission of Grant Applications to Grants.Gov**

Once the E-Business POC has authorized privileges to the AOR, the AOR will receive an email notification that they have been given authorization. The AOR may then proceed to submit applications to Grants.Gov. For application instructions, go to <http://www.grants.gov/Apply>. The training demonstration at <http://www.grants.gov/CompleteApplication> will assist AORs in the application process.

Remember that you must open and complete the Application for Federal Assistance (Research and Related) SF 424 (R&R) first, as this form will automatically populate data fields in other forms (See section 2a for supplemental instructions). If you encounter any problems, contact customer support at 1-800-518-4726 or at [support@grants.gov](mailto:support@grants.gov). If you forget your user name or password, follow the instructions provided in the Credential Provider tutorial. Tutorials may be printed by right-clicking on the tutorial and selecting “Print”. The User Guide is found at: [http://www.grants.gov/help/user\\_guides.jsp](http://www.grants.gov/help/user_guides.jsp).